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Anvisa gmp guidelines pdf

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All manufacturers of products under sanitary surveillance must follow Good Manufacturing Practices (GMP) rules set by Anvisa as a regulatory requirement, covering various sectors such as medicines, medical devices, personal hygiene products, cosmetics, and food. The specifics for each sector include: - Medicines: Resolution RDC 658/2022 along with associated guidelines - Radiopharmaceuticals: Compliance with Resolution RDC 658/2022 and Normative Instruction IN 128/2022 - Medicinal Gases: Adherence to Resolution RDC 658/2022 and Normative Instruction IN 129/2022 - Herbal products: Following Resolution RDC 658/2022 along with Normative Instruction IN 130/2022 - Active Pharmaceutical Ingredients (APIs): Implementation of Resolution RDC 654/2022 for GMP practices and Resolution RDC 204/2006 for Good Distribution Practices - Pharmaceutical Excipients: Compliance with Resolution RDC 34/2015 - Personal Hygiene Products, Cosmetics, and Fragrances: Adherence to Resolution RDC 48/2013 - Sanitizers: Following the requirements outlined in Resolution RDC 47/2013 - Food: Implementation of Resolution RDC 275/2002 for Technical Standards; Ordinance SVS/MS 326/1997 for Hygienic-Sanitary Conditions; and Ordinance MS 1428/1993 for Quality, Identification Standards, and Guidelines for Good Services Production - Medical Devices: Compliance with Resolution RDC 665/2022 (general aspects), Resolution RDC 687/2022 (administrative processes), and other minimum requirements set in specific resolutions like Resolution RDC 291/2019 Additional standards may apply based on the specifications of the medical devices, such as those from ABNT, ISO, or INMETRO. The GMP Certificate issued by Anvisa confirms that an establishment meets the technical requirements for commercializing a product according to current laws, but its regular functioning is not contingent upon this certification. Establishments making sanitary-controlled products must comply with GMP requirements. Various tools aid in granting certificates, including inspection reports from Anvisa or state health agencies. Resolution RDC 497/2021 outlines procedures for obtaining GMP Certification by Anvisa, covering Drugs Products, Medical Devices, and other items. This certification is valid for two years. Currently, information on Drug Products (Medicines), APIs, Personal Hygiene Products, Cosmetics, Fragrances, and Sanitizers can be found on the provided links. A dashboard displays information on inspection procedures to verify compliance with GMP and other relevant details. Anvisa conducts international inspections to ensure Good Manufacturing Practices for products to be imported and sold in Brazil, including Drug Products, Medical Devices, and APIs. A valid GMP Certificate is necessary for market authorization. For Medical Devices, inspections apply only to Risk Classes III and IV manufacturers. Foreign companies seeking renewal must request it every two years through their Brazilian representative. However, a risk analysis may determine if re-inspections are needed or if the certification can be renewed based on documental analysis. Foreign companies looking to export products to Brazil need to obtain a GMP Certificate, as stated in Resolution RDC nº 7 from January 27th, 2000. They cannot directly make arrangements for certificate issuance with Anvisa and must have a partner company legally established in Brazil responsible for the imported and distributed products within the country. The dashboard mentioned provides information on inspection procedures to verify GMP compliance, alongside general rules outlined in Resolution RDC 497/2021. Resolution RDC 687/2022 specifically addresses administrative processes for granting GMP Certification for Medical Devices manufacturers (Risk Classes III and IV). Manufacturing sites that produce finished devices under their name or for another company, those responsible for releasing the finished device related to at least one production stage, and software as a medical device manufacturing sites are subject to GMP certification. This includes packaging considered as sterile barrier systems of products declared as sterile and manufacturing units for in vitro diagnostic medical devices performing impregnation, laminating, or cutting steps. This Resolution continues on-site inspections by Anvisa after a priority analysis and issues GMP Certificates through one of three procedures: evaluation of a valid audit report, risk analysis supporting certificate issuance based on presented documents, or inspection reports issued by Anvisa following an on-site inspection. GMP guidance across countries varies significantly, with no single global standard in place. Various regulatory bodies, such as ANVISA in Brazil, issue their own guidelines for Good Manufacturing Practices (GMP). In Brazil, companies must submit pre-inspection information six months prior to a license application date. This includes detailed product and facility information, as well as geographical coordinates. For renewal certifications every two years, ANVISA assesses risks and decides on the need for additional inspections. These inspections are rigorous, with inspectors focusing on facility operations and management involvement in SOPs and manufacturing documents. They also examine HVAC systems, quality control procedures, and employee training. ANVISA inspectors prefer multi-product inspections and are well-trained and experienced. During an inspection, they look for clear validation guidelines and specifications, including analytical methods and hygiene conditions. Separate production lines for human and veterinary medicinal products are also expected. After the inspection, a report is generated within 30 days, but no certification is issued immediately. A successful inspection leads to the issuance of a GMP certificate.